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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>GLAND PHARMA LIMITED,<br><br>Defendant. | Civil Action No. 14-XXXX (XXX) (XXX) |

**COMPLAINT**

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations, and on information and belief as to all other facts.

## NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 that arises out of Defendant's request for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis's Reclast® product prior to the expiration of U.S. Patent No. 8,052,987 ("the '987 patent").

## THE PARTIES

### A. Novartis

3. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '987 patent.

### B. Gland Pharma Limited

4. Gland Pharma Limited ("Gland") is a corporation organized and existing under the laws of India. Its principal place of business is in Hyderabad, India.

5. Upon information and belief, Gland has submitted to the FDA at least one ANDA seeking approval to market a zoledronic acid product, including a generic version of Novartis's branded product Zometa®. Upon information and belief, the FDA has approved at least one of Gland's ANDAs relating to zoledronic acid and Gland is developing and manufacturing generic versions of branded pharmaceutical products, including a generic version of Zometa, for distribution in the United States, including in New Jersey.

6. Gland has availed itself of the legal protections of the State of New Jersey by, among

other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

7. Upon information and belief, Gland also submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 204217, seeking approval to market a generic version of Reclast. This ANDA is the subject of this complaint.

## JURISDICTION AND VENUE

8. This action seeks to enforce federal patent rights under federal law. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over defendant Gland for the following reasons, among others:

a) Defendant Gland sells, manufactures, imports and/or distributes generic drugs for distribution in New Jersey, and is seeking approval to sell and/or distribute a generic version of Reclast in New Jersey;

b) Novartis, which will be harmed by the defendant's actions, is domiciled in New Jersey;

c) Defendant Gland has systematic and continuous contacts with New Jersey, in that, among other things, it sells, manufactures, imports and/or distributes generic drugs for distribution in New Jersey; and

d) Defendant Gland has previously acquiesced to personal jurisdiction and asserted counterclaims in this jurisdiction, including in related matter *Novartis*

*Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated).

## STATEMENT OF FACTS

### A. Novartis's Branded Product

11. The active ingredient in Reclast is zoledronic acid. Reclast was first approved by the FDA in 2007 and is approved to treat osteoporosis, a condition in which bones become weakened, and Paget's disease, a clinically rare genetic condition that disrupts the normal cycle of bone turnover.

12. Reclast is administered intravenously as a 5 mg dose diluted in standard buffer media. Reclast is sold only in a liquid form that is fully diluted and ready to be administered. Unopened, Reclast has a shelf life of three years.

### B. The Patent-In-Suit

13. The '987 patent, entitled "Method of administering bisphosphonates," was duly and legally issued on November 8, 2011 and is owned by Novartis. A copy of the '987 patent is attached as Exhibit A.

14. The '987 Patent is listed in connection with Reclast in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, the defendant has actual or constructive knowledge of the patent.

### C. Gland's Proposed Generic Product

15. By letter dated February 5, 2014, Gland notified Novartis that it had submitted to the FDA ANDA No. 204217 pursuant to 21 U.S.C. § 355(j)(2)(B).

16. In the notice letter, Defendant Gland stated that its application included a Paragraph IV Certification with respect to the '987 patent, alleging it is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Defendant's generic Reclast product.

17. This action is being commenced before expiration of forty-five days from Novartis's receipt of Defendant Gland's notice letter.

**COUNT I (INFRINGEMENT OF THE '987 PATENT)**

18. Upon information and belief, Defendant Gland knew of the '987 patent when it submitted ANDA No. 204217, and knows or is willfully blind to the fact that its actions will induce or contribute to direct infringement of the '987 patent.

19. Defendant Gland's submission of ANDA No. 204217, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of its generic Reclast products before the expiration of the '987 patent, is an act of infringement of the '987 patent under 35 U.S.C. § 271(e)(2).

20. Use of Defendant Gland's generic Reclast product in accordance with and as directed by Defendant Gland's proposed labeling would infringe one or more claims of the '987 patent.

21. Upon information and belief, upon FDA approval of its ANDA, Defendant Gland will indirectly infringe the '987 patent by making, using, offering to sell, and selling its generic Reclast product in the United States and/or importing this product into the United States.

22. Upon information and belief, upon FDA approval of its ANDA, Defendant Gland will actively induce infringement of the '987 patent in violation of 35 U.S.C. § 271(b) by making, using, offering to sell, selling, importing and/or distributing its generic Reclast product in the United States.

23. Upon information and belief, upon FDA approval of its ANDA, Defendant Gland will also contribute to infringement of the '987 patent by others, by knowingly offering to sell, selling, or distributing within the United States or importing into the United States generic Reclast, which has no substantial non-infringing uses, in violation of 35 U.S.C. § 271(c).

24. There is an actual and justiciable case or controversy between Novartis and Defendant Gland concerning the validity and infringement of the '987 patent. Novartis is entitled to a declaration that Defendant Gland's manufacture, use, sale, offer for sale, and/or importation of its generic Reclast product will infringe, contribute to the infringement of and/or actively induce the infringement of one or more claims of the '987 patent, and that the claims of the '987 patent are not invalid.

25. Unless Defendant Gland is enjoined from infringing the '987 patent, actively inducing infringement of the '987 patent, and/or contributing to the infringement by others of the '987 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Novartis requests entry of judgment in its favor and against the defendant as follows:

1. Declaring that the '987 patent is not invalid;

2. Declaring that the Defendant has infringed, directly or indirectly, one or more claims of the '987 patent;

3. Damages or other monetary relief to Novartis if Defendant Gland engages or continues to engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of generic versions of Reclast prior to the latest expiration date of the '987 patent,

including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. Declaring that Defendant by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of generic versions of Reclast has willfully infringed the claims of the '987 patent;

5. An order permanently enjoining Defendant, and its affiliates, subsidiaries, officers, agents, servants and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic versions of Reclast until after the latest expiration date of the patent relating to approved presentations, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled; and

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: March 21, 2014

*s/William J. O'Shaughnessy*

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

I certify that to the best of my knowledge, the matter in controversy is the subject of:

- *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated) filed on June 27, 2012 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Accord Healthcare Inc.*, Civil Action No. 2:13-cv-07178-SDW-MCA filed on November 26, 2013 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Fresenius Kabi USA, LLC*, Civil Action No. 2:13-cv-07914-SDW-MCA filed on December 27, 2013 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Pharmaceutics International, Inc.*, Civil Action No. 2:14-cv-01347-SDW-MCA filed on March 3, 2014 in the District of New Jersey.

Dated: March 21, 2014

*s/William J. O'Shaughnessy*

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